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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,627	11/29/2005	Wolfgang Glaesner	X15984	6106

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EXAMINER

NIEBAUER, RONALD T

ART UNIT	PAPER NUMBER
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1609

NOTIFICATION DATE	DELIVERY MODE
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05/10/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary

Application No.

10/558,627

Applicant(s)

GLAESNER ET AL.

Examiner

Ronald T. Niebauer

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 16-19 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 2-8, 16-19 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/29/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-8) and SEQ ID NO:1 as the species in the reply filed on 3/21/07 is acknowledged. The traversal is on the ground(s) that a single general inventive concept exists among the species. Applicants argue that the specific fusion proteins have unity of invention due to particular properties. This is not found persuasive because it does not describe how the prior art is overcome nor does it show that all alternatives have a common property.

The species have different properties since the claimed invention (for example claim 1) includes various substitutions and there would be no expectation from the knowledge in the art that each member would behave in the same manner. From MPEP section 1850:

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)
 - (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
 - (B)
 - (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together. In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge

Art Unit: 1609

in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Applicants argument that specific fusion proteins have different properties from the non-substituted (increased potency, increased in vivo stability, etc.) shows a priori that no common function is shared among all of the alternatives. Note that one of the criteria listed above is that 'all alternatives have a common property of activity'.

Applicants argue that the claimed invention makes a contribution over the prior art. This is not found persuasive because it does not describe how the prior art is overcome since the arguments are not drawn to the broad generic claim.

Glaesner et al. (2002 as disclosed in the IDS) teach (specifically claim 27 page 104, but many other claims as well) a heterologous fusion protein comprising a GLP-1 compound and the Fc portion of an immunoglobulin. In the specification (page 1) a GLP-1 compound is defined as 'numerous GLP-1 analogs and derivatives' and a wide range of analogs are described (pages 7-34). Further, claim 30 (page 105) teaches variations, particularly those at positions 8, 22, and 36 of the current invention. The prior art also teaches Fc fusions (claim 27, 50-54, 74-78). Applicant discusses specific changes in the Fc region, but as claimed the invention reads on the non-substituted version of Fc (compare page 7 line 15 of the specification).

The properties of proteins are a feature of the protein. If the prior art teaches a protein, a new property of that protein does not make a contribution over the prior art. The applicant argues that modifications at position 8 (to Gly) and 22 (to Glu) make a contribution over the art. These modifications are taught in the prior art: positions 8 and

Art Unit: 1609

22 can be Gly and Glu respectively in claim 30 and these modifications are specifically listed as a possibility on page 20 line 14 (Gly8-Glu22-GLP-1). The prior art also teaches Fc fusions (claim 27, 50-54, 74-78). Therefore, the claimed invention makes no contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-8, 16-19, 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/21/07. It is noted that the restriction requirement (2/21/07) stated:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Heterologous fusion protein. Each of the groups refers to a heterologous fusion protein. Applicant should specify a single species such that the heterologous fusion protein is uniquely defined. For example, a single species could be identified by a specific amino acid sequence of the GLP-1 analog, a linker sequence (if any), and the Fc fragment sequence.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added.

Applicant identified a GLP-1 analog sequence, but did not elect a linker sequence or Fc fragment sequence. Therefore the elected heterologous fusion protein is: GLP-1 analog of SEQ ID NO:1, no linker, Fc of any sequence. Applicant did not identify claims readable on the elected species. Claim 1 is readable on the elected species.

Art Unit: 1609

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Requirements

37 CFR 1.821(e) and 1.824 state the requirements for submission of sequences in computer readable form. The computer readable form received lists a title of 'Fusion proteins' which is not the title of this application (although it is the title of application 10558862). The computer readable form lists SEQ ID NO:1 as having a length of 230. The paper listing and claims and specification list SEQ ID NO:1 as having a length of 31. Appropriate correction is required.

Specification

The use of the trademark EPIMATRIX (page 5 line 31) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Glaesner et al. (WO 02/46227 as cited in IDS). It is noted that the publication date is June 13 2002 and the art is by 'another' since Micanovic and Tschang are not listed on the current application. The current invention, based on the elected species as discussed above, is: GLP-1 analog of SEQ ID NO:1, no linker, Fc of any sequence. Glaesner et al. (2002 as disclosed in the IDS) teach (specifically claim 27 page 104, but many other claims as well) a heterologous fusion protein comprising a GLP-1 compound and the Fc portion of an immunoglobulin. In the specification (page 1) a GLP-1 compound is defined as 'numerous GLP-1 analogs and derivatives' and a wide range of analogs are described (pages 7-34). Further, claim 30 (page 105, also compare page 20) teaches variations, particularly those at positions 8, 22, and 36 of the current invention. The prior art also teaches Fc fusions (claim 27, 50-54, 74-78). Therefore claim 1 is anticipated by Glaesner et al.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Glaesner et al. (WO 02/46227 as cited in IDS). It is noted that according to MPEP 706.02(f)(1) the 102(e) date is the international filing date, in this case November 29, 2001. The art is by 'another' since Micanovic and Tschang are not listed on the current application. The current invention, based on the elected species as discussed above, is: GLP-1 analog of SEQ ID NO:1, no linker, Fc of any sequence. Glaesner et al. (2002 as disclosed in the IDS) teach (specifically claim 27 page 104, but many other claims as well) a heterologous fusion protein comprising a GLP-1 compound and the Fc portion of an immunoglobulin. In the specification (page 1) a GLP-1 compound is defined as 'numerous GLP-1 analogs and derivatives' and a wide range of analogs are described (pages 7-34). Further, claim 30 (page 105, also compare page 20) teaches variations, particularly those at positions 8, 22, and 36 of the current invention and elected species. The prior art also teaches Fc fusions (claim 27, 50-54, 74-78). Therefore claim 1 is anticipated by Glaesner et al.

The applied reference has a common assignee/inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10558862. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of Application No. 10558862 recites a heterologous fusion protein comprising a peptide fused to the Fc portion of an immunoglobulin. Although the peptide is not further defined in the claim, on page 11 line 5 an example is given in which a GLP-1 analog (Gly8-Glu22-Gly36-GLP-1) is identified. The GLP-1 analog is identical to that claimed in the current application. One having ordinary skill in the art would have been motivated to use this particular GLP-1 analog and have expectation for success with the heterologous fusion protein because it is stated as an

Art Unit: 1609

embodiment in the specification. Taken together, it would have been obvious to one of skill in the art to use the combinations of the current application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1609

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rtn


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SUPERVISORY PATENT EXAMINER
5-3-07